

**CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT**

**SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT OF 1986
(PROPOSITION 65)**

**NOTICE TO INTERESTED PARTIES
September 26, 2003**

**Request for Information on a Chemical to be Considered by the
OEHHA Science Advisory Board's Carcinogen Identification Committee**

The California Environmental Protection Agency's Office of Environmental Health Hazard Assessment (OEHHA) is the lead agency for the implementation of the Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65; Health and Safety Code Section 25249.5 *et seq.*).

The Carcinogen Identification Committee (CIC) of OEHHA's Science Advisory Board identifies chemicals for addition to the list of chemicals known to the State to cause cancer, which pursuant to Proposition 65 must be updated annually. The Committee serves as the State's qualified experts for determining whether a chemical has been clearly shown through scientifically valid testing according to generally accepted principles to cause cancer.

At its December 17, 2002 meeting, the CIC recommended that OEHHA, as resources are available, prepare individual hazard identification documents for each of the statin drugs and present them to the CIC at a future meeting. The CIC at that time would consider each of the statin drugs individually for possible listing.

On February 21, 2003, OEHHA published a notice in the *California Regulatory Notice Register* (CRNR) (Register 03, No.8-Z) soliciting information that may be relevant to the evaluation of six statin drugs which had been at one time or another approved for use in the U.S., namely atorvastatin calcium, cerivastatin sodium, fluvastatin sodium, lovastatin, pravastatin sodium, and simvastatin. Information has been received that OEHHA is reviewing as it prepares a draft hazard identification document for each statin drug. Since the close of the comment period, a new statin drug, rosuvastatin calcium, has been approved for use by the U.S. Food and Drug Administration. In light of the CIC's December 2002 recommendation, OEHHA initiates a 60-day data call-in period for rosuvastatin calcium listed below:

CHEMICAL	CAS No.
Rosuvastatin calcium	147098-20-2

Interested parties or members of the public wishing to provide information relevant to the assessment of carcinogenicity for this chemical should forward such information to the address given below. This period will end on **Tuesday, November 25, 2003**. The information received during this data call-in period will be reviewed and considered by OEHHA as it develops the draft cancer hazard identification document on rosuvastatin calcium.

OEHHA welcomes public participation and public input as part of these scientific assessments. Notification of the availability of the hazard identification documents for each statin drug and the time, date, location, and agenda of the meeting of the CIC where these chemicals will be considered will also be provided in subsequent notices published in the CRNR and posted on the OEHHA web site at www.oehha.ca.gov. It is anticipated that the draft hazard identification documents will be made available for a 60-day comment period prior to the Committee meeting at which these chemicals will be considered.

Relevant information on this chemical should be sent in triplicate by mail or fax to:

Cynthia Oshita
Office of Environmental Health Hazard Assessment
Proposition 65 Implementation
P.O. Box 4010
1001 I Street, 19th floor
Sacramento, California 95812-4010
FAX (916) 323-8803
(916) 445-6900

In order to be considered, the relevant information must be postmarked (if sent by mail) or received at OEHHA (if delivered in person or sent by FAX) by 5:00 p.m. on Tuesday, November 25, 2003.